KA/: G-GPO / 2515 / WPP-47 / 2009-2011



ಕರ್ನಾಟಕ ರಾಜ್ಯಪತ್ರ

ಅಧಿಕೃತವಾಗಿ ಪ್ರಕಟಿಸಲಾದುದು

ಸಂಪುಟ ೧೪೫	ಬೆಂಗಳೂರು, ಗುರುವಾರ, ಡಿಸೆಂಬರ್ ೯, ೨೦೧೦ (ಮಾರ್ಗಶಿರ ೧೮, ಶಕವರ್ಷ ೧೯೩೨)	ಸಂಚಿಕೆ ೪೮

ಭಾಗ – ೪

ಕೇಂದ್ರದ ವಿಧೇಯಕಗಳು ಮತ್ತು ಅವುಗಳ ಮೇಲೆ ಪರಿಶೀಲನಾ ಸಮಿತಿಯ ವರದಿಗಳು, ಕೇಂದ್ರದ ಅಧಿನಿಯಮಗಳು ಮತ್ತು ಅಧ್ಯಾದೇಶಗಳು, ಕೇಂದ್ರದ ಸರ್ಕಾರದವರು ಹೊರಡಿಸಿದ ಸಾಮಾನ್ಯ ಶಾಸನಬದ್ಧ ನಿಯಮಗಳು ಮತ್ತು ಶಾಸನಬದ್ಧ ಆದೇಶಗಳು ಮತ್ತು ರಾಷ್ಟ್ರಪತಿಯವರಿಂದ ರಚಿತವಾಗಿ ರಾಜ್ಯ ಸರ್ಕಾರದವರಿಂದ ಪುನಃ ಪ್ರಕಟವಾದ ಆದೇಶಗಳು

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 35 ಕೇಶಾಪ್ರ 2010, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 21ನೇ ಅಕ್ಟೋಬರ್, 2010

2010ನೇ ಸಾಲಿನ ಆಗಸ್ಟ್ 19ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ–II, ಸೆಕ್ಷೆನ್ 1 ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ The Clinical Establishments (Registration and Regulation) Act, 2010 (No. 23 of 2010) ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF LAW AND JUSTICE

(Legislative Department)

New Delhi, the August 19, 2010/Sravana 28, 1932 (Saka)

The following Act of Parliament received the assent of the President on the 18th August, 2010, and is hereby published for general information :-

THE CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2010.

No. 23 of 2010

(18th August, 2010*)*

An Act to provide for the registration and regulation of clinical establishments in the country and for matters connected therewith or incidental thereto.

WHEREAS, it is considered expedient to provide for the registration and regulation of clinical establishments with a view to prescribe minimum standards of facilities and services which may be provided by them so that mandate of article 47 of the Constitution for improvement in public health may be achieved;

AND WHEREAS, Parliament has no power to make laws for the States with respect to any of the matters aforesaid except as provided in articles 249 and 250 of the Constitution;

AND WHEREAS, in pursuance of clause (1) of article 252 of the Constitution, resolutions have been passed by all the Houses of the Legislatures of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim to the effect that the matters aforesaid should be regulated in those States by Parliament by law;

BE it enacted by Parliament in the Sixty-first Year of the Republic of India as follows :-

CHAPTER I

PRELIMINARY

1. Short title, application and commencement :- (I) This Act may be called the Clinical Establishments (Registration and Regulation) Act, 2010.

(2) It applies, in the first instance, to the whole of the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim and the Union territories; and it shall apply to such other State which adopts this Act by resolution passed in that behalf under clause (I) of article 252 of the Constitution.

(3) It shall come into force at once in the States of Arunachal Pradesh, Himachal Pradesh, Mizoram and Sikkim and the Union territories, on such date as the Central Government may, by notification, appoint and in any other State which adopts this Act under clause (I) of article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union territory, mean the date on which this Act comes into force in such State or Union territory:

Provided that different dates may be appointed for different categories of clinical establishments and for different recognised systems of medicine.

2. Definitions :- In this Act, unless the context otherwise requires,-

(a) "authority" means the district registering authority set-up under section 10;

(b) "certificate" means certificate of registration issued under section 30;

(c) "clinical establishment" means-

(i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or

(ii) a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not,

and shall include a clinical establishment owned, controlled or managed by-

(a) the Government or a department of the Government;

(b) a trust, whether public or private;

(c) a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government;

(d) a local authority; and

(e) a single doctor,

but does not include the clinical establishments owned, controlled or managed by the Armed Forces.

Explanation.-For the purpose of this clause "Armed Forces" means the forces constituted under the Army Act, 1950, (46 of 1950) the Air Force Act, 1950 (45 of 1950) and the Navy Act,. 1957; (62 of 1957)

(d)" emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in-

(i) placing the health of the individual or, with respect to a pregnant women, the health of the woman or her unborn child, in serious jeopardy; or

(ii) serious impairment to bodily functions; or

(iii) serious dysfunction of any organ or part of a body;

(e) "National Council" means the National Council for clinical establishments established under section 3;

(f) "notification" means a notification published in the Official Gazette;

(g) "prescribed" means prescribed by rules made under this Act by the Central Government or, as the case may be, the State Government;

(h) "recognised system of medicine" means Allopathy, Yoga, Naturopathy, Ayurveda, Homoeopathy, Siddha and Unani System of medicines or any other system of medicine as may be recognised by the Central Government;

(i) "register" means the register maintained by the authority, State Government and the Central Government under sections 37, 38 and 39 respectively of this Act containing the number of clinical establishments registered;

(j) "registration" means to register under section 11 and the expression registration or registered shall be construed accordingly;

(k) "rules" means rules made under this Act;

(l) "Schedule" means the Schedule appended to this Act;

(m) "standards" means the conditions that the Central Government may prescribe under section 12, for the registration of clinical establishments;

(n) "State Government", in relation to a Union territory, means the Administrator thereof appointed under article 239 of the Constitution; and

(o) "to stabilise (with its grammatical variations and cognate expressions)" means, with respect to an emergency medical condition specified in clause (d), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a clinical establishment.

CHAPTER II

THE NATIONAL COUNCIL FOR CLINICAL ESTABLISHMENTS

3. Establishment of National Council :- (1) With effect from such date as the Central Government may, by notification appoint in this behalf, there shall be established for the purposes of this Act, a Council to be called the National Council for clinical establishments.

(2) The National Council shall consist of -

(a) Director-General of Health Service, Ministry of Health and Family Welfare, ex officio, who shall be the Chairperson;

(b) four representatives out of which one each to be elected by the-

(i) Dental Council of India constituted under section 3 of the Dentists Act, 1948; (16 of 1948)

(ii) Medical Council of India constituted under section 3 of the Indian Medical Council Act, 1956; (102 of 1956)

(iii) Nursing Council of India constituted under section 3 of the Indian Nursing Council Act, 1947; (48 of 1947)

(iv) Pharmacy Council of India constituted under section 3 of the Pharmacy Act, 1948; (8 of 1948)

(c) three representatives to be elected by the Central Council of Indian Medicine representing the Ayurveda, Siddha and Unani systems of medicine constituted under section 3 of the Indian Medicine Central Council Act, 1970; (48 of 1970)

(d) one representative to be elected by the Central Council of Homoeopathy constituted under section 3 of the Homoeopathy Central Council Act, 1973; (59 of 1973)

(e) one representative to be elected by the Central Council of the Indian Medical Association;

(f) one representative of Bureau of the Indian Standards constituted under section 3 of the Bureau of Indian Standards Act, 1986; (63 of. 1986)

(g) two representatives from the Zonal Council set-up under Section 15 of the States Reorganisation Act, 1956; (37 of 1956)

(h) two representatives from the North-Eastern Council set-up under section 3 of the North-Eastern Council Act, 1971; (84 of 1971)

(i) one representative from the line of paramedical systems excluding systems that have been given representation under clause (b);

(j) two representatives from National Level Consumer Group to be nominated by the Central Government;

(k) one representative from the Associations of Indian Systems of Medicines relating to Ayurveda, Siddha and Unani to be nominated by the Central Government;

(l) the Secretary-General of the Quality Council of India, ex officio.

(3) The nominated members of the National Council shall hold office for three years but shall be eligible for re-nomination for maximum of one more term of three years.

(4) The elected members of the National Council shall hold office for three years, but shall be eligible for re-election:

Provided that the person nominated or elected, as the case may be, shall hoId office for such period till he holds appointment of the office by virtue of which he was nominated or elected to the council.

(5) The members of the National Council shall be entitled for such allowances as may be prescribed by the Central Government.

(6) The National Council may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(7) The National Council shall meet at least once in three months.

(8) The National Council may constitute sub-committees and may appoint to such sub-committee, as it deems fit, persons, who are not members of the National Council, for such period, not exceeding two years, for the consideration of particular matters.

(9) The functions of the National Council may be exercised notwithstanding any vacancy therein .

. 10) The Central Government shall appoint such person to be the Secretary· of the National Council as the Central Government may prescribe, and may provide the National Council with such other secretarial and other staff as the Central Government considers necessary.

4. Disqualifications for appointment as member :- A person shall be disqualified for being appointed as a member of the National Council if he-

(a) has been convicted and sentenced to imprisonment for an offence which, in the opinion of the Central Government, involves moral turpitude; or

(b) is an undischarged insolvent; or

(c) is of unsound mind and stands so declared by a competent court; or

(d) has been removed or dismissed from the service of the Government or a Corporation owned or controlled by the Government; or

(e) has, in the opinion of the Central Government, such financial or other interest in the Council as is likely to affect prejudicially the discharge by him of his functions as a member.

5. Functions of National Council :- The National Council Shall-

(a) compile and publish a National Register of clinical establishments within two years from the date of the commencement of this Act;

(b) classify the clinical establishments into different categories;

(c) develop the minimum standards and their periodic review;

(d) determine within a period of two years from its establishment, the first set of standards for ensuring proper healthcare by the clinical establishments;

(e) collect the statistics in respect of clinical establishments;

(f) perform any other function determined by the Central Government from time to time.

6. Power to seek advice or assistance :- The National Council may associate with itself any person or body whose assistance or advice it may desire in carrying out any of the provisions of this Act.

7. National Council to follow consultative process :- The National Council shall follow a consultative process for determining the standards and for classification of clinical establishments in accordance with such procedure as may be prescribed.

CHAPTER III

REGISTRATION AND STANDARDS FOR CLINICAL ESTABLISHMENTS.

8. State Council of clinical establishments :- (1) Every State Government shall by notification constitute a State Council for clinical establishments or the Union territory Council for clinical establishments, as the case may be.

(2) The State Council or the Union territory Council, as the case may be, shall consist

of the following members, namely:-

(a) Secretary, Health - ex officio. who shall be the Chairman;

(b) Director of Health Services - ex officio member-secretary;

(c) Directors of different streams of Indian Systems of Medicine--ex officio members;

(d) one representative each to be elected by the executive committee of

(I) State Medical Council of India;

(ii) State Dental Council of India;

(iii) State Nursing Council of India;

(iv) State Pharmacy Council of India;

(e) three representatives to be elected by the Executive of the State Council or the Union territory Council, as the case may be, of Indian Medicine representing the Ayurveda, Siddha and Unani systems of medicine;

(f) one representative to be elected by the State Council of the Indian Medical Association:

(g) one representative from the line of paramedical systems;

(h) two representatives from State level consumer groups or reputed non- Governmental organisations working in the field of health.

(3) The nominated member of the State Council or the Union territory Council, as the case may be, shall hold office for a term of three years, bus shall be eligible for re-nomination for maximum of one more term of three years.

(4) The elected members of the State Council or the Union territory Council, as the case may be, shall hold office for three years, but shall be eligible for re-election:

Provided that the person nominated or elected, as the case may be, shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the State Council or the Union territory Council, as the case may be.

(5) The State Council of the Union territory Council shall perform the following functions, namely:-

(a) compiling and updating the State Registers of clinical establishment;

(b) sending monthly returns for updating the National Register;

(c) representing the State in the National Council;

(d) hearing of appeals against the orders of the authority; and

(e) publication on annual basis a report on the State of implementation of standards within their respective States.

9. Providing information to National Council :- It shall be the responsibility of the State Council for clinical establishments to compile and update the State Register of clinical establishments of the State and further to send monthly returns in digital format for updating the National Register.

10. Authority for registration :- (1) The State Government shall, by notification, set-up an authority to be called the district registering authority for each district for registration of clinical establishments, with the following members, namely:--

(a) District Collector - Chairperson;

(b) District Health Officer - Convenor;

(c) three members with such qualifications and on such terms and conditions as may be prescribed by the Central Government.

(2) Notwithstanding anything contained in sub-section (1), for the purposes of provisional registration of clinical establishments under section 14, the District Health Officer or the Chief Medical Officer (by whatever name called) shall exercise the powers of the authority as per procedure that may be prescribed.

11. Registration for clinical establishments :- No person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of this Act.

12. Condition for registration :- (1) For registration and continuation, every clinical establishment shall fulfil the following conditions, namely:-

(i) the minimum standards of facilities and services as may be prescribed;

(ii) the minimum requirement of personnel as may be prescribed;

(iii) provisions for maintenance of records and reporting as may be prescribed;

(iv) such other conditions as may be prescribed.

(2) The clinical establishment shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilise the emergency medical condition of any individual who comes or is brought to such clinical establishment.

13. Classification of clinical establishments :- (1) Clinical establishment of different systems shall be classified into such categories, as may be prescribed by the Central Government, from time to time.

(2) Different standards may be prescribed for classification of different categories referred to in sub-section (1):

Provided that in prescribing the standards for clinical establishments, the Central Government shall have regard to the local conditions.

CHAPTER IV

PROCEDURE FOR REGISTRATION

14. Application for provisional certificate of registration :- (1) For the purposes of registration of the clinical establishment under section 10, an application in the prescribed proforma along with the prescribed fee shall be made to the authority.

(2) The application shall be filed in person or by post or online.

(3) The application shall be made in such form and shall be accompanied by such details as may be prescribed under this Act or rules made thereunder.

(4) If any clinical establishment is in existence at the time of the commencement of this Act, an application for its registration shall be made within one year from the date of the commencement of this Act and a clinical establishment which comes into existence after commencement of this Act, shall apply for permanent registration within a period of six months from the date of its establishment.

(5) If any clinical establishment is already registered under any existing law requiring registration of such establishments, even then it shall apply for registration as referred to in sub-section (1).

15. Provisional certificate :- The authority shall, within a period of ten days from the date of receipt of such application, grant to the applicant a certificate of provisional registration in such form and containing such particulars and such information, as may be prescribed.

16. No inquiry prior to provisional Registration :- (1) The authority shall not conduct any inquiry prior to the grant of provisional registration.

(2) Not withstanding the grant of the provisional certificate of registration, the authority shall, within a period of forty-five days from the grant of provisional registration, cause to be published in such manner, as may be prescribed, all particulars of the clinical establishment so registered provisionally.

17. Validity of provisional registration :- Subject to the provisions of section 23, every provisional registration shall be valid to the last day of the twelfth month from the date of issue of the certificate of registration and such registration shall be renewable.

18. Display of certificate of registration :- The certificate shall be kept affixed in a conspicuous place in the clinical establishment in such manner so as to be visible to every one visiting such establishment.

19. Duplicate certificate :- In case the certificate is lost, destroyed, mutilated or damaged, the authority shall issue a duplicate certificate on the request of the clinical establishment and on the payment of such fees as may be prescribed.

20. Certificate to be non- transferable :- (l) The certificate of registration shall be non-transferable.

(2) In the event of change of ownership or management, the clinical establishment shall inform the authority of such change in such manner as may be prescribed.

(3) In the event of change of category, or location, or on ceasing to function as a clinical establishment, the certificate of registration in respect of such clinical establishment shall be surrendered to the authority and the clinical establishment shall apply afresh for grant of certificate of registration.

21. Publication of expiry of registration :- The authority shall cause to be published within such time and in such manner, as may be prescribed, the names of clinical establishments whose registration has expired.

22. Renewal of registration :- The application for renewal of registration shall be made thirty days before the expiry of the validity of the certificate of provisional registration and, in case the application for renewal is made after the expiry of the provisional registration, the authority shall allow renewal of registration on payment of such enhanced fees, as may be prescribed.

23. Time limit for provisional registration :- Where the clinical establishments in respect of which standards have been notified by the Central Government, provisional registration shall not be granted or renewed beyond,-

(i) the period of two years from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of this Act;

(ii) the period of two years from the date of notification of the standards for clinical establishments which come into existence after the commencement of this Act but before the notification of the standards; and

(iii) the period of six months from the date of notification of standards for clinical establishments which come into existence after standards have been notified.

. **24. Application for permanent registration :-** Application for permanent registration by a clinical establishment shall be made to the authority in such form and be accompanied by such fees, as may be prescribed.

25. Verification of application :- The clinical establishment shall submit evidence of having complied with the prescribed minimum standards in such manner, as may be prescribed.

26. Display of information for filing objections :- As soon as the clinical establishment submits the required evidence of having complied with the prescribed minimum standards, the authority shall cause to be displayed for information of the public at large and for filing objections, if any, in such manner, as may be prescribed, all evidence submitted by the clinical establishment of having complied with the prescribed minimum standards for a period of thirty days before processing for grant of permanent registration.

27. Communication of objections :- If objections are received within the period referred to in the preceding section, such objections shall be communicated to the clinical establishment for response within a period of forty-five days.

28. Standards for permanent registration :- Permanent registration shall be granted only when a clinical establishment fulfils the prescribed standards for registration by the Central Government.

29. Allowing or disallowing of registration :- The authority shall pass an order immediately after the expiry of the prescribed period and within the next thirty days thereafter either-

(a) allowing the application for permanent registration; or

(b) disallowing the application:

Provided that the authority shall record its reasons, if it disallows an application, for permanent registration.

30. Certificate of permanent registration :- (I) The authority shall, if it, allows an application of the clinical establishment, issue a certificate of permanent registration in such ·form and containing such particulars, as may be prescribed.

(2) The certificate shall be valid for a period of five years from the date of issue.

(3) For the purposes of sub-section (I), the provisions of sections 18, 19, 20 and 21 shall also apply.

(4) The applications for renewal of permanent registration shall be made within six months before the expiry of the validity of the certificate of permanent registration and, in case the application of renewal is not submitted within the stipulated period, the authority may allow renewal of registration on payment of such enhanced fees and penalties as may be prescribed.

31. Fresh application for permanent registration :- The disallowing of an application for permanent registration shall not debar a clinical establishment from applying afresh for permanent registration under section 24 and after providing such evidence, as may be required, of having rectified the deficiences on which grounds the earlier application was disallowed.

32. Cancellation of registration :- (l) If, at any time after any clinical establishment has been registered, the authority is satisfied that,-

(a) the conditions of the registration are not being complied with; or

(b) the person entrusted with the management of the clinical establishment has been convicted of an offence punishable under this Act,

it may issue a notice to the clinical establishment to show cause within three months' time as to why its registration under this Act should not be cancelled for the reasons to be mentioned in the notice.

(2) If after giving a reasonable opportunity to the clinical establishment, the authority is satisfied that there has been a breach of any of the provisions of this Act or the rules made thereunder, it may, by an order, without prejudice to any other action that it may take against such clinical establishment, cancel its registration.

(3) Every order made under sub-section (2) shall take effect-

(a) where no appeal has been preferred against such order immediately on the expiry of the period prescribed for such appeal; and

(b) where such appeal has been preferred and it has been dismissed from the date of the order of such dismissal:

Provided that the authority, after cancellation of registration for reasons to be recorded in writing, may restrain immediately the clinical establishment from carrying on if there is imminent danger to the health and safety of patients.

33. Inspection of registered clinical establishments :- (1) The authority or an officer authorised by it shall have the right to cause an inspection of, or inquiry in respect of any registered clinical establishment, its building, laboratories and equipment and also of the work conducted or done by the clinical establishment, to be made by such multi-member inspection team as it may direct and to cause an inquiry to be made in respect of any other matter connected with the clinical establishment and that establishment shall be entitled to be represented thereat.

(2) The authority shall communicate to the clinical establishment the views of that authority with reference to the results of such inspection or inquiry and may, after ascertaining the opinion of the clinical establishment thereon, advise that establishment upon the action to be taken.

(3) The clinical establishment shall report to the authority, the action, if any, which is proposed to be taken or has been taken upon the results of such inspection or inquiry and such report shall be furnished within such time, as the authority may direct.

(4) Where the clinical establishment does not, within a reasonable time, take action to the satisfaction of the authority, it may, after considering any explanation furnished or representation made by the clinical establishment, issue such directions within such time as indicated in the direction, as that authority deems fit, and the clinical establishment shall comply with such directions.

34. Power to Center :- The authority or an officer authorised by it may, if there is any reason to suspect that anyone is carrying on a clinical establishment without registration, enter and search in the manner prescribed, at any reasonable time and the clinical establishment, shall offer reasonable facilities for inspection or inquiry and be entitled to be represented thereat:

Provided that no such person shall enter the clinical establishment without giving notice of his intention to do so.

35. Levy of fee by State Government :- The State Government may charge fees for different categories of clinical establishments, as may be prescribed.

36. Appeal:- (1) Any person, aggrieved by an order of the registering authority refusing to grant or renew a certificate of registration or revoking a certificate of registration may, in such manner and within such period as may be prescribed, prefer an appeal to the State Council:

Provided that the State Council may entertain an appeal preferred after the expiry of the prescribed period if it is satisfied that the appellant was prevented by sufficient cause from preferring the appeal in time.

(2) Every appeal under sub-section (1) shall be made in such form and be accompanied by such fee as may be prescribed.

CHAPTER V

REGISTER OF CLINICAL ESTABLISHMENTS

37. Register of clinical establishments :- (1) The authority shall within a period of two years from its establishment, compile, publish and maintain in digital format a register of clinical establishments, registered by it and it shall enter the particulars of the certificate so issued in a register to be maintained in such form and manner, as may be prescribed by the State Government.

(2) Each authority, including any other authority set-up for the registration of clinical establishments under any other law for the time being in force, shall supply in digital format to the State Council of Clinical establishments a copy of every entry made in the register of clinical establishments in such manner, as may be prescribed to ensure that the State Register is constantly up-to-date with the registers maintained by the registering authority in the State.

38. Maintenance of State Register of clinical establishments :- (1) Every State Government shall maintain in digital and in such form and containing such particulars, as may be prescribed by the Central Government a register to be known as the State Register of clinical establishments in respect of clinical establishments of that State.

(2) Every State Government shall supply in digital format to the Central Government, a copy of the State Register of clinical establishments and shall inform the Central Government all additions to and other amendments in such register made, for a particular month by the 15th day of the following month.

39. Maintenance of National Register of clinical establishments :- The Central Government shall maintain in digital format an All India Register to be called as the National Register of clinical establishments that shall be an amalgam of the State Register of clinical establishments maintained by the State Governments and shall cause the same to be published in digital format.

CHAPTER VI

PENALTIES

40. Penalty :- Whoever contravenes any provision of this Act shall, if no penalty is provided elsewhere, be punishable for the first offence with fine which may extend to ten thousand rupees, for any second offence with fine which may extend to fifty thousand rupees and for any subsequent offence with fine which may extend to five lakh rupees.

41. Monetary penalty for non-registration :- (1) Whoever carries on a clinical establishment without registration shall, on first contravention, be liable to a monetary penalty up to fifty thousand rupees, for second contravention with a monetary penalty which may extend to two lakh rupees and for any subsequent contravention with a monetary penalty which may extend to five lakh rupees.

(2) Whoever knowingly serves in a clinical establishment which is not duly registered under this Act, shall be liable to a monetary penalty which may extend to twenty-five thousand rupees.

(3) For the purpose of adjudging under sub-sections (1) and (2), the authority shall hold an inquiry an the prescribed manner after giving any person concerned a reasonable opportunity of being heard for the purpose of imposing any monetary penalty.

(4) While holding an inquiry the authority shall have power to summon and enforce the attendance of any person acquainted with the facts and circumstances of the case to give evidence or to produce any document which in the opinion of the authority, may be useful for or relevant to the subject matter of the inquiry and if, on such inquiry, it is satisfied that the person has failed to comply with the provisions specified in sub-sections (1) and (2), it may by order impose the monetary penalty specified in those sub-sections to be deposited within thirty days of the order in the account referred to in sub-section (8) of section 42.

(5) While determining the quantum of monetary penalty, the authority shall take into account the category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated.

(6) Any person aggrieved by the decision of the authority may prefer an appeal to the State Council within a period of three months from the date of the said decision.

(7) The manner of filing the appeal referred to in sub-section (6) shall be such as may be prescribed.

42. Disobedience of direction, obstruction and refusal of information :- (1) Whoever wilfully disobeys any direction lawfully given by any person or authority empowered under this Act to give such direction, or obstructs any person or authority in the discharge of any functions which such person or authority is required or empowered under this Act to discharge, shall be liable to a monetary penalty which may extend to five lakh rupees.

(2) Whoever being required by or under this Act to supply any information wilfully withholds such information or gives information which he knows to be false or which he does not believe to be true, shall be liable to a monetary penalty which may extend to five lakh rupees.

(3) For the purpose of adjudging under sub-sections (1) and (2), the authority shall hold an inquiry in the prescribed manner after giving any person concerned a reasonable opportunity of being heard for the purpose of imposing any monetary penalty.

(4) While holding an inquiry the authority shall have power to summon and enforce the attendance of any person acquainted with the facts and circumstances of the case to give evidence or to produce any document which in the opinion of the authority, may be useful for or relevant to the subject matter of the inquiry and if, on such inquiry, it is satisfied that the person has failed to comply with the provisions specified in sub-sections(1) and (2),it may by order impose the monetary penalty specified in those sub-sections to be deposited within thirty days of the order in the account referred to in sub-section (8).

(5) While determining the quantum of monetary penalty, the authority shall take into account the category, size and type of the clinical establishment and local conditions of the area in which the establishment is situated.

(6) Any person aggrieved by the decision of the authority may prefer an appeal to the State Council within a period of three months from the date of the said decision.

(7) The manner of filing the appeal referred to in sub-section (6) shall be such as may be prescribed.

(8) The monetary penalty levied under sections 41 and 42 shall be credited to such account as the State Government may by order specify in this behalf.

43. Penalty for minor deficiencies :- Whoever contravenes any provision of this Act or any rule made thereunder resulting in deficiencies that do not pose any imminent danger to the health and safety of any patient and can be rectified within a reasonable time, shall be punishable with fine which may extend to ten thousand rupees.

44. Contravention by companies :- (1*)* Where a person committing contravention of any of the provisions of this Act or of any rule made thereunder is a company, every person who, at the time the contravention was committed, was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the contravention and shall be liable to fine:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment if he proves that the contravention was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such contravention.

(2) Notwithstanding anything contained in sub-section (I), where a contravention of any of the provisions of this Act or of any rule made thereunder has been committed by a company and it is proved that the contravention has taken place with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that contravention and shall be liable to fine.

Explanation: -For the purpose of this section,-

(a) "company" means a body corporate and includes a firm or other association of individuals; and

(b) "director", in relation to a firm, means a partner in the firm.

45. Offences by Government Departments :- (1) Where an offence under this Act has been committed by any Department of Government within a period of six months after the commencement of this Act, the Head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render such Head of the Department liable to any punishment if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a Department of Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the Head of the Department, such officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

46. Recovery of fine :- Whoever fails to pay the fine, the State Council of clinical establishment may prepare a certificate signed by an officer authorised by it specifying the fine due from such person and send it to the Collector of the District in which such person owns any property or resides or carries on his business and the said Collector, on receipt of such certificate, shall proceed to recover from such person the amount specified thereunder, as if it were an arrear of land revenue.

CHAPTER VII

MISCELLANEOUS

47. Protection of action taken in good faith :- (1) No suit, prosecution or other legal proceedings shall lie against any authority or any member of the National Council or State Council or any officer authorised in this behalf in respect of anything, which is in good faith done or intended to be done in pursuance of the provisions of this Act or any rule made thereunder.

(2) No suit or other legal proceedings shall lie against a State Government or the Central Government in respect of any loss or damage caused or likely to be caused by anything which is in good faith done or intended to be done in pursuance of the provisions of this Act or any rule made thereunder.

48. Furnishing of returns, etc :- Every clinical establishment shall, within such time or within such extended time, as may be prescribed in that behalf, furnish to the authority or the State Council or the National Council such returns or the statistics and other information in such manner, as may be prescribed by the State Government, from time to time.

49. Power to give directions :- Without prejudice to the foregoing provisions of this Act, the authority shall have the power to issue such directions, including furnishing returns, statistics and other information for the proper functioning of clinical establishments and such directions shall be binding.

50. Employees of the authority, etc., to be public servants :- Every employee of the authority, the National Council and the State Council shall be deemed to, when acting or purporting to act in pursuance of any of the provisions of this Act, be public servants within the meaning of section 21 of the Indian Penal Code. (45 of 1860)

51. Power to remove difficulties :- (1) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as may appear to it to be necessary or expedient for removal of the difficulty:

Provided that no such order shall be made after the expiry of a period of two years from the date of commencement of this Act.

(2) Every order made under this section shall, as soon as may be after it is made, be laid before each House of Parliament.

52. Power of Central Government to make rules :- (1) The Central Government may, by notification, make rules for carrying out all or any of the provisions of this Act.

(2) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:-

(a) allowances for the members of the National Council under sub-section (5) of section 3;

(b) appointment of such person to be the Secretary of the State Council by the Central Government under sub-section (10) of section 3;

(c) the determination of standards and for classification of clinical establishments under section 7;

(d) the qualification and the terms and conditions for the members of the authority under clause (c) of sub-section (1) of section 10;

(e) the procedure under which the powers of the authority may be exercised by the District Health Officer or Chief Medical Officer for the purpose of provisional registration of clinical establishment under sub-section (2) of section 10;

(f) the minimum standards of facilities and services under clause (i) of sub-section (1) of section 12;

(g) the minimum number of personnel under clause (ii) of sub-section (1) of section 12:

(h) the maintenance of records and reporting by the clinical establishment under clause (iii) of sub-section (1) of section 12;

(i) other conditions for registration and continuation of clinical establishment under clause (iv) of sub-section (1) of section 12;

(j) classification of clinical establishment under sub-section (1) of section 13;

(k) the different standards for classification of clinical establishments under sub-section (2) of section 13;

(l) the minimum standards for permanent registration under section 28;

(m) the form and particulars to be contained in the register to be maintained under section 38.

53. Laying of rules :- Every rule made by the Central Government under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be ; so, however, that any such modification or annulment shall be with out prejudice to the validity of anything previously done under that rule.

54. Power of State Government to make rules :- (1) The State Government may, by notification, make rules for carrying out in respect of matters which do not fall within the purview of section 52.

(2) In particular and without prejudice to the generality of the foregoing power, such rules may provide for all or any of the following matters, namely:-

(a) the proforma and the fee to be paid for registration under sub-section (1) of section 14 ;

(b) the form and details of application under sub-section (3) of section 14;

(c) the particulars and information contained in certificate of provisional registration under section 15;

(d) the manner of publication of all particulars of the clinical establishments proposed to be registered under sub-section (2) of section 16;

(e) the fees to be paid to issue a duplicate certificate under section 19;

(f) the change of ownership or management to be informed by the clinical establishment to the authority under sub-section (2) of section 20;

(g) the manner in which the authority shall publish the names of the clinical establishments whose registration expired under section 21;

(h) the enhanced fees to be charged for renewal after expiry of the provisional registration under section 22;

(i) the form of the application and fees to be charged by the State Government under section 24;

(j) the manner of submitting evidence of the clinical establishments having complied with the minimum standards under section 25;

(k) the manner of displaying information of the clinical establishments having complied with the minimum standards for filing objection under section 26;

(l) the expiry of period specified in section 29;

(m) the form and particulars of the certificate of registration under section 30;

(n) the period within which an appeal shall be preferred under clause (a) of sub-section (3) of section 32;

(o) the manner of entry and search of clinical establishment under section 34;

(p) the fees to be charged by the State Government for different categories of clinical establishments under section 35;

(q) the manner and the period within which an appeal may be preferred to the State Council under sub-section (1) of section 36;

(r) the form and the fee to be paid for an appeal under sub-section (2) of section 36;

(s) the form and the manner in which the register to be maintained under sub-section (1) of section 37;

(t) the manner of supply to the State Council in digital format the entry made in the register of clinical establishment under sub-section (2) of section 37;

(u) the manner of holding an inquiry by the authority under sub-section (3) of sections 41 and 42;

(v) the manner of filing the appeal under sub-section (7) of sections 41 and 42;

(w) the manner and the time within which the information is to be furnished to the authority or the State Council or the National Council as the case may be, under section 48;

(x) any other matter which is required to be or may be prescribed by the State Government.

55. Laying of rules :- Every rule made by the State Government under this section shall be laid, as soon as may be after it is made, before each House of the State Legislature where it consists of two Houses, or where such Legislature consists of one House, before that House.

56. Savings :- (1) The provisions of this Act shall not apply to the States in which the enactments specified in the Schedule are applicable.

Provided that the States in which the enactments referred to in sub-section (1) are applicable, and such States subsequent to the commencement of this Act, adopts this Act under clause (1) of article 252 of the Constitution, the provisions of this Act shall, subsequent to such adoption, apply in that State.

(2) The Central Government may, as and when consider necessary, by notification amend the Schedule.

THE SCHEDULE

[See section 56]

1. The Andhra Pradesh Private Medical Care Establishments (Registration and Regulation) Act, 2002.
2. The Bombay Nursing Homes Registration Act, 1949.
3. The Delhi Nursing Homes Registration Act, 1953.
4. The Madhya Pradesh Upcharya Griha Tatha Rujopchar Sanbabdu Sthapamaue (Registrikaran Tha Anugyapan) Adhiniyam, 1973.
5. The Manipur Homes and Clinics Registration Act, 1992.
6. The Nagaland Health Care Establishments Act, 1997.
7. The Orissa Clinical Establishments (Control and Regulation) Act, 1990.
8. The Punjab State Nursing Home Registration Act, 1991.
9. The West Bengal Clinical Establishment Act, 1950.

V. K. BHASIN,

Secy. to the Govt. of India.

ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,

ಆರ್. ಆಂಜಿನಿ,

ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ

ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,

PR. No. 60 ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಸಚಿವಾಲಯ

ಅಧಿಸೂಚನೆ

ಸಂಖ್ಯೆ: ಸಂವ್ಯಶಾಇ 36 ಕೇಶಾಪ್ರ 2010, ಬೆಂಗಳೂರು, ದಿನಾಂಕ: 21ನೇ ಅಕ್ಟೋಬರ್, 2010

2010ನೇ ಸಾಲಿನ ಆಗಸ್ಟ್ 23ನೇ ದಿನಾಂಕದ ಭಾರತ ಸರ್ಕಾರದ ಗೆಜೆಟ್‌ನ ವಿಶೇಷ ಸಂಚಿಕೆಯ ಭಾಗ–II ಸೆಕ್ಷೆನ್ 1 ರಲ್ಲಿ ಪ್ರಕಟವಾದ ಈ ಕೆಳಕಂಡ The Securities and Insurance Laws (Amendment and Validation) Act, 2010 (No. 26 of 2010) ಅನ್ನು ಸಾರ್ವಜನಿಕರ ಮಾಹಿತಿಗಾಗಿ ಕರ್ನಾಟಕ ರಾಜ್ಯ ಪತ್ರದಲ್ಲಿ ಮರು ಪ್ರಕಟಿಸಲಾಗಿದೆ.

MINISTRY OF LAW AND JUSTICE

(Legislative Department)

New Delhi, August 23, 2010/Bhadra 1, 1932 (Saka)

The following Act of Parliament received the assent of the President on the 20th August 2010, and is hereby published for general information:-

THE SECURITIES AND INSURANCE LAWS (AMENDMENT AND VALIDATION) ACT, 2010

(No. 26 of 2010)

(20th August, 2010)

An Act further to amend the Reserve Bank of India Act, 1934, the Insurance Act, 1938, the Securities Contracts (Regulation) Act, 1956 and the Securities and Exchange Board of India Act, 1992.

BE it enacted by Parliament in the Sixty-first Year of the Republic of India as follows:-

CHAPTER I

PRELIMINARY

1. Short title and commencement :-

(1) This Act may be called the Securities and Insurance Laws (Amendment and Validation) Act, 2010.

(2) It shall be deemed to have come into force on the 18th day of June, 2010.

CHAPTER II

AMENDMENT TO THE RESERVE BANK OF INDIA ACT, 1934

2. Insertion of new chapter IIIE in Act 2 of 1934 :- After Chapter IIID of the Reserve Bank of India Act, 1934, the following Chapter shall be inserted, namely :-

CHAPTER IIIE

JOINT MECHANISM

45Y. Joint Mechanism :- (1) Notwithstanding anything contained in this Act or the Securities and Exchange Board of India Act, 1992 (15 of 1992) or any other law for the time being in force, if any difference of opinion arises as to whether-

(i) any instrument, being derivative referred to in clause (a) or money market instrument referred to in clause (b) or repo referred to in clause (c) or reverse repo referred to in clause (d) or securities referred to in clause (e) of section 45U of this Act; or

(ii) any instrument, being policy of life insurance under the Insurance Act, 1938, (4 of 1938) or the rules of regulations made thereunder, or, scrips or any other securities referred to in sub-clauses (i), (ia),(ib),(ic),(id),(ie),(ii),(iia) and (iii) of clause (h) of section 2 of the Securities Contracts (Regulation) Act, 1956, (42 of 1956)

is hybrid or composite instrument, having a component of money market investment or securities market instrument or a component of insurance or any other instrument referred to in clause (i) or clause (ii) and falls within the jurisdiction of the Reserve Bank of India or the Securities and Exchange Board of India established under section 3 of the' Securities and Exchange Board of India Act, 1992 (15 of 3 1992) or the Insurance Regulatory and Development Authority established under section 3 of the Insurance Regulatory and Development Authority Act, 1999 (4I of 1999) or the Pension Fund Regulatory and Development Authority constituted by the Resolution of the Government of India number F.No. I (6)2007-PR, dated the 14th November, 2008, such difference of opinion shall be referred to a Joint Committee consisting of the following, namely:-

(a) the Union Finance Minister - ex officio Chairperson;

(b) the Governor, Reserve Bank of India - ex officio Vice-Chairperson;

(c) the Secretary, Department of Economic Affairs in the Ministry of Finance, Government of India - ex officio Member;

(d) the Secretary, Department of Financial Services in the Ministry of Finance, Government of India – ex officio Member;

(e) the Chairperson, Insurance Regulatory and Development Authority – ex officio Member;

(f) the Chairman, Securities and Exchange Board of India - ex officio Member;

(g) the Chairperson, Pension Fund Regulatory and Development Authority - ex officio Member.

(2) The Secretary, Department of Financial Services in the Ministry of Finance, Government of India shall be the convener of the meetings of the Joint Committee referred to in sub-section (1).

(3) In case of any difference of opinion referred to in sub-section (1), any Member of the Joint Committee referred to in clauses (b), (e), (f) or (g) of that sub-section may make a reference to the Joint Committee.

(4) The Joint Committee shall follow such procedure as it may consider expedient and give, within a period of three months from the date of reference made under sub-section (3), its decisions thereon to the Central Government.

(5) The decision of the Joint Committee shall be binding on the Reserve Bank of India, the Securities and Exchange Board of India, the Insurance Regulatory and Development Authority and the Pension Fund Regulatory and Development Authority.".

CHAPTER III

AMENDMENT TO THE INSURANCE ACT, 1938

3. Amendment of section 2 of Act 4 of 1938 :- In the Insurance Act, 1938, in section 2, after clause (11), the following Explanation shall be inserted and shall be deemed to have been inserted with effect from the 9th day of April, 2010, namely:-

'Explanation:- For the removal of doubts, it is hereby declared that "Life insurance business" shall include any unit linked insurance policy or scrips or any such instrument or unit, by whatever name called, which provides a component of investment and a component of insurance issued by an insurer referred to in clause (9) of this section.'.

CHAPTER IV

AMENDMENT TO THE SECURITIES CONTRACTS (REGULATION) ACT, 1956

4. Amendment Of Section 2 of Act 42 of 1956 :- In the Securities Contracts (Regulation) Act, 1956, in section 2, in clause (h), after sub-clause (id), the following *Explanation* shall be inserted and shall be deemed to have been inserted with effect from the 9th day of April, 2010, namely :-

'Explanation.- For the removal of doubts, it is hereby declared that "securities" shall not include any unit linked insurance policy or scrips or any such instrument or unit, by whatever name called, which provides a combined benefit risk on the life of the persons and investment by such persons and issued by an insurer referred to in clause (9) of section 2 of the Insurance Act, 1938. (4 of 1938).;

CHAPTER V

AMENDMENT TO THE SECURITIES AND EXCHANGE BOARD OF INDIA ACT, 1992

5. Amendment of section 12 of Act 15 of 1992 :- In the Securities and Exchange Board of India Act, 1992, in section 12, in sub-section (l B), the following Explanation shall be inserted and shall be deemed to have been inserted with effect from the 9th day of April, 2010, namely :-

"Explanation.- For the removal of doubts, it is hereby declared that, for the purposes of this section, a collective investment scheme or mutual fund shall not include any unit linked insurance policy or scrips or any such instrument or unit, by whatever name called, which provides a component of investment besides the component of insurance issued by an insurer.".

CHAPTER VI

MISCELLANEOUS

6. Validation :- Notwithstanding anything contained in any judgment, decree or order of any court, tribunal or other authority, the provisions of section 2 of the Insurance Act, 1938 (4 of 1938) or section 2 of the Securities Contracts (Regulation) Act, 1956 (42 of 1956) or section 12 of the Securities and Exchange Board of India Act, 1992,(15 of 1992) as amended by this Act, shall have and shall be deemed to always have effect for all purposes as if the provisions of the said Acts, as amended by this Act, had been in force at all material times and accordingly any unit linked insurance policy or scrips or any such instrument or unit, by whatever name called, issued or purported to have been issued at any time before the 9th day of April,2010, shall be deemed and always deemed to have been validly issued and shall not be called in question in any court of law or other authority solely on the ground that it was issued without a certificate of registration under any law for the time being in force or without following any procedure under any law for the time being in force, by an insurer or any other person.

7. Repeal and savings :- (1) The Securities and Insurance Laws (Amendment and Validation) Ordinance, 2010 (Ord 3 of 2010) is hereby repealed.

(2) Notwithstanding such repeal, anything done or any action taken under the Reserve Bank of India Act, 1934 (2 of 1934) or the Insurance Act, 1938 (4 of 1938) or the Securities Contracts (Regulation) Act, 1956 (42 of 1956) or the Securities and Exchange Board of India Act, 1992 (15 of 1992) as amended by the said Ordinance, shall be deemed to have been done or taken under the corresponding provisions of those Acts, as amended by this Act.

V. K. BHASIN,
Secy. to the Govt. of India.
ಕರ್ನಾಟಕ ರಾಜ್ಯಪಾಲರ ಆದೇಶಾನುಸಾರ ಮತ್ತು ಅವರ ಹೆಸರಿನಲ್ಲಿ,
ಆರ್. ಆಂಜಿನಿ,
ಸಹಾಯಕ ಪ್ರಾರೂಪಕಾರ ಮತ್ತು ಪದನಿಮಿತ್ತ
ಸರ್ಕಾರದ ಉಪ ಕಾರ್ಯದರ್ಶಿ,
ಸಂಸದೀಯ ವ್ಯವಹಾರಗಳು ಮತ್ತು ಶಾಸನ ರಚನೆ ಇಲಾಖೆ.

PR. No. 61